Thomas Jefferson University | Jefferson Medical College

Jerome M. Cotler, MD
The Everett J. and Marian Gordon
Professor of Orthopaedic Surgery

130 South 9th Street
Suite 106
Philadelphia, PA 19107-5233

215-955-2001
Fax: 215-955-2008

December 6, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

To Whom It May Concern:

It has recently come to my attention that the FDA is considering change that would allow it to regulate some types of allograft as medical devices. I truly don't know what is behind this consideration, but I would like to speak only to bone, which is the medium in which I work.

If information is available that the current process for the FDA regulation of bone as a tissue for safety falls short, perhaps you could share that with me. Otherwise, I think that the current process is very adequate and satisfactory and has worked well for the patient in many, many instances. One of my concerns would be the ability to clear the FDA's pre-market requirements as well as clinical trials for documentation. Limitation of bone products would truly prove a hardship to many patients and their treatment protocols. I do believe that the biologic process in many instances is far better than some of the metallic devices that frequently are interchanged clinically where bone would suffice.

I do hope you will consider my concerns in your deliberations.

Sincerely,

Jerome M. Cotler, M.D.

97N-4845

C95

Thomas Jefferson University | Jefferson Medical College | Jefferson University Physicians

Jefferson Orthopaedics and Sports Medicine
130 South 9th Street, Suite 106
Philadelphia, PA 19107-5233

PRESORTED FIRST CLASS
PHILADELPHIA
DEC 07 '98
PB METER
0243
WILM DE

Document Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

AUTO